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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/975,714

10/11/2001

Paul Jacobs

ASP-41

1051

27777

7590

03/21/2003

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EXAMINER

MCKANE, ELIZABETH L

ART UNIT

PAPER NUMBER

1744

DATE MAILED: 03/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/975,714

Applicant(s)

JACOBS ET AL.

Examiner

Leigh McKane

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-7, 9, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Cummings et al (U.S. Patent No. 4,744,951).

As to claims 1, 2, 7, 9, and 18, Cummings et al teaches a method of sterilizing wherein an article is placed into a sterilizing chamber 22, the chamber is evacuated (dried), a dilute (0.05-5%) aqueous solution of H₂O₂ is introduced into an enclosure 10 having a diffusion restriction 20 in fluid communication with the chamber 22 and vaporized. Thereafter, water vapor is drawn off through port 14 to increase the ratio of H₂O₂ to water. The H₂O₂ is then furnished to the article within evacuated chamber 22 for sterilization. See col.3, lines 29-55.

With respect to claims 3-6, Cummings et al discloses a preferred final concentration of hydrogen peroxide (50-80%), which encompasses the claimed ratios.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 10-17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cummings et al.

Cummings et al discloses that "conditions within the chamber" are controlled to cause the preferential vaporization of water from the solution. Those in the art know these "conditions" to be temperature and pressure, as shown in the Examples. It is known to those in the art that vaporization of a component of a solution occurs when the vapor pressure of the component exceeds that of its surroundings. This can be achieved by increasing the vapor pressure of the component through two means: heating the solution or lowering the surrounding pressure. Thus,

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it would have been obvious control both of these parameters in any desired combination or order in order to control vaporization of the water from the solution.

Although Cummings et al does not teach repeating the steps of vaporization and drawing the water vapor off, Cummings et al does disclose a preferred final concentration of hydrogen peroxide (50-80%) and if this range was not reached after a first vaporization and drawing off, it would have been obvious to repeat the steps as necessary to reach the desired concentration.

7. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cummings et al as applied to claim 12 above, and further in view of Spencer et al (U.S. Patent No. 5,656,238).

Cummings et al is silent with respect to generating a plasma during the drying step. However, Spencer et al teaches that it was known in the art to generate a plasma to dry a sterilization chamber (see col.2, lines 36-48). Spencer et al indicates that the plasma enhances the drying of the chamber or items therein. Since Cummings et al is concerned with concentrating the hydrogen peroxide it would have been obvious to remove all water from the chamber which would dilute the hydrogen peroxide and thus, would have been obvious to use a plasma to assure complete removal of water from the chamber.

Conclusion

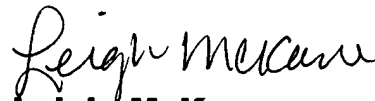
8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kowanko teaches that it was known in the art to use preferential vaporization to create a gaseous sterilant from a liquid solution or mixture. See col.4, line 65 to col.5, line 10.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 703-305-3387. The examiner can normally be reached on Monday-Wednesday (7:15 am-4:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.


Leigh McKane
Primary Examiner
Art Unit 1744

elm
March 19, 2003